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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/074,974	02/13/2002	Sheldon R. Pinnell	SKIC001-	6893

7590

08/26/2003

Lynn E. Barber
Post Office Box 16528
Fort Worth, TX 76162

EXAMINER

PATTEN, PATRICIA A

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 08/26/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicant(s)

10/074,974

Applicant(s)

PINNELL ET AL.

Examiner

Patricia A Patten

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 July 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16, 18-21 and 23-28 is/are pending in the application.
- 4a) Of the above claim(s) 1-15, 27 and 28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☒ Claim(s) 18-20 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

DETAILED ACTION

RCE Practice

A request for continued examination under 37 CFR § 1.114, including the fee set forth in 37 CFR § 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR § 1.114, and the fee set forth in 37 CFR § 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR § 1.114. Applicant's submission filed on 7/11/03 has been entered.

Claims 1- 16, 18-21 and 23-28 are pending in the application.

Claims 1-15 and 27-28 were withdrawn from further consideration on the merits as being drawn to a non-elected invention in Paper No. 4.

Claims 16, 18-21 and 23 -26 were presented for examination on the merits.

Because Applicants' arguments pertain solely to the previous rejections, and because the previous rejections have been removed, these arguments are considered moot and will not be addressed. A new rejection follows.

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Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16, 19, 21, 23, 24, 25 and 26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Specifically, claim 16 has been amended to recite 'at least about ½ % of a non-aqueous solvent extract of olive leaves'. There is a lack of written description in the originally presented Specification for such an embodiment. Because claims 19-26 depend upon claim 16, and do not limit claim 16 to an embodiment which was adequately described in the Instant specification as filed, these claims are also rejected under this statute for lacking written description.

Specifically, the term 'non-aqueous solvent extract' has not been specifically described as being a part of the intended invention. As such, it is thought that Applicants were not in possession of such a product at the time the invention was made. First, the question is, what is a non-aqueous solvent extract of olive leaves?

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The Instant specification did not particularly define this term, and thus, the Examiner shall conclude that the term is given its plain meaning: olive leaves extracted with a non-aqueous solvent. Although Applicants do disclose that the final product was obtained via a non-aqueous extraction process, this process does not only include a non-aqueous extraction. For example, pages 6 and 7 of the Instant specification describe the process for making an extract of olive leaves which pertains to the invention of the application; grinding olive leaves, addition of an anti-enzymatic compound, extracting with a non-aqueous organic solvent, filtering, boiling in water, filtering, combining with alcohol and charcoal, boiling, filtering and reconcentrating.

See Gentry Gallery, 134 F.3d at 1480, 45 USPQ2d at 1503; *In re Sus*, 306 F.2d 494, 504, 134 USPQ 301, 309 (CCPA 1962) “[O]ne skilled in this art would not be taught by the written description of the invention in the specification that any aryl or substituted aryl radical’ would be suitable for the purposes of the invention but rather that only certain aryl radicals and certain specifically substituted aryl radicals [i.e., aryl azides] would be suitable for such purposes.”) (emphasis in original).

The term ‘extract’ is a concept which may broadly describe Applicant’s invention: i.e., the Detailed Description of the Invention states: “The present invention provides a method of obtaining an olive-leaf extract”. This term is deemed appropriate, albeit broad, since the final product obtained from the method could be considered an ‘extract’ since it has been *drawn out* of its original placement in the plant material. However, the term ‘non-aqueous solvent extract’ is a specific term, as explained *supra*, which

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describes a particular extract. Accordingly, the skilled artisan would understand this term to mean a product formed by only a non-aqueous solvent extraction. However, as described in the Instant specification, this is not the case.

The Instant specification gives no guidance or consideration to any product made by a simple non-aqueous organic solvent extraction of olive leaves. On the contrary, the Instant specification describes making topical compositions with an extract of olive leaves which contains on average 6-10% oleuropein. This particular extract was made via several extraction processes, an anti-enzymatic treatment (boiling in alcohol and treatment with acid and magnesium sulfate) boiling in water and filtration. This product is deemed (considering the known, and accepted meaning of 'non-aqueous solvent extract of olive leaves') absolutely different than a simple non-aqueous solvent extract of olive leaves.

Applicant may argue that because the method does describe a non-aqueous extraction step of olive leaves that this constitutes sufficient written description. However, these steps are deemed intermediary, and do not form the crux of the final product obtained from all of the steps in the method. Furthermore, the Instant specification does not suggest the use of any of the intermediate products in any fashion. Even if the process was considered complete after the first extraction with a non-aqueous solvent, the process began with an anti-enzymatic step of treatment with boiling alcohol and addition of magnesium sulfate as well as acid treatment. The simple term 'non-aqueous solvent extract' does not elude to the incorporation of these other

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essential steps which actually form the final product of the extraction of the Instant specification. Moreover, the skilled artisan would reasonably conclude that a non-aqueous solvent extract would include active enzymes which were not denatured by boiling in alcohol and treatment with magnesium sulfate and acid.

Allowable Subject Matter

Claims 18 and 20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Patricia Patten, whose telephone number is (703)308-1189. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (703) 306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306. The official After final fax phone number is (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

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August 25, 2003

A handwritten signature in black ink, appearing to read "Patricia Patten". The signature is written in a cursive style with a large, looping initial "P".

Patricia Patten